



OPTIMAL ACADEMY

GMP training for confident daily practice

From a two-hour introduction to a five-day applied workshop.

Pharmaceuticals, biopharmaceuticals
and advanced therapy manufacturing



Learn with experienced practitioners

Over 50 years' combined GMP experience.
Live online, on-site or blended. Pricing on request.

Choose your learning pathway

Courses can stand alone or form a role-based programme.

G01	GMP essentials Recognise GMP responsibilities and everyday risks.	2 hours
G02	Good documentation and data integrity Review and correct a sample record with a clear audit trail.	3 hours
G03	Deviation writing, RCA and CAPA Write a deviation and evidence-based CAPA plan.	1 day
G04	OOS / OOT investigations Build an investigation plan and justified conclusion.	2 days
G05	Qualification and validation Prepare a risk-based validation outline and test traceability.	2 days
G06	Cleaning validation Build a grouping, sampling and acceptance rationale.	1 day
G07	Contamination control and aseptic readiness Review a contamination-control case and prioritise actions.	2 days
G08	Audit and inspection readiness Practise evidence presentation and a response action plan.	1 day
G09	Technology transfer and analytical lifecycle Map transfer risks and analytical evidence requirements.	2 days
G10	GMP for biopharma and advanced therapies Apply GMP thinking to a product-specific case.	2 days
G11	Applied GMP quality workshop Produce a connected investigation and validation evidence pack.	5 days

Duration guide: a full day is 6 facilitated learning hours, excluding breaks. The five-day workshop provides 30 facilitated hours.

Detailed scope, prerequisites and assessment are agreed before booking.

Foundation and daily quality practice

Practical records and decisions form the core of each course.

G01 GMP essentials

2 hours

Who: New starters, contractors and staff needing a refresher.

Topics: Patient and product protection, roles, hygiene, contamination, material flow, records and escalation.

Practice: Knowledge check and a personal action list.

G02 Good documentation and data integrity

3 hours

Who: Operators, QA/QC, engineering and document owners.

Topics: Clear entries, corrections, attributable records, contemporaneous recording, audit trails and ALCOA+ concepts.

Practice: Review a sample batch or laboratory record.

G03 Deviation writing, RCA and CAPA

1 day

Who: Quality, production, maintenance and engineering teams.

Topics: Problem statement, immediate actions, evidence collection, causal analysis, impact assessment and CAPA effectiveness.

Practice: Draft a deviation, root-cause rationale and CAPA plan.

G08 Audit and inspection readiness

1 day

Who: Department leads, quality staff and process owners.

Topics: Evidence retrieval, interview practice, observation response, ownership and action closure.

Practice: Conduct a mock interview and prepare a response plan.

Technical and specialist courses

Select modules for the systems, products and responsibilities at your site.

G04 OOS / OOT investigations

2 days

Initial laboratory assessment, manufacturing investigation, hypothesis testing, retest/resample rationale, impact and reporting. Practice: an evidence-based investigation plan and conclusion.

G05 Qualification and validation

2 days

Lifecycle planning, risk and system impact, requirements, DQ/IQ/OQ/PQ, process validation and change control. Practice: a validation outline with traceability.

G06 Cleaning validation

1 day

Product grouping, worst case, limits, sampling, recovery and hold times. Practice: a cleaning-validation strategy exercise.

G07 Contamination control and aseptic readiness

2 days

Contamination pathways, facility/utilities, personnel, monitoring and aseptic interventions. Practice: a case-based contamination-control action plan.

G09 Technology transfer and analytical lifecycle

2 days

Knowledge transfer, receiving-site gaps, process/equipment equivalence, method transfer and lifecycle monitoring. Practice: a transfer risk and evidence map.

G10 GMP for biopharma and advanced therapies

2 days

Tailored product/process risks, contamination control, starting materials, traceability and complex manufacturing interfaces. Practice: a product-specific risk workshop.

Prerequisites: relevant GMP or technical experience. G01 is recommended for newcomers. Specialist courses require an agreed product and process context.

Five-day applied GMP workshop

G11 • 30 facilitated hours • A connected case, from event to justified action

DAY 1 **GMP, records and the event**

Assess a fictional manufacturing event. Review records, define the problem and decide immediate containment.

Output: Event timeline and deviation draft.

DAY 2 **OOS / OOT and investigation logic**

Examine laboratory and manufacturing evidence. Plan hypothesis tests and consider the basis for retesting or resampling.

Output: Investigation plan and evidence log.

DAY 3 **Root cause, CAPA and risk**

Test causal explanations, assess wider impact and develop proportionate corrective and preventive actions.

Output: Root-cause rationale, risk assessment and CAPA plan.

DAY 4 **Validation and change control**

Map requirements to evidence. Review qualification, process and cleaning-validation interfaces within the case.

Output: Validation outline and change-control impact review.

DAY 5 **Technical writing and challenge**

Complete the report, present conclusions and respond to a mock quality-review panel. Agree workplace application.

Output: Reviewed evidence pack and a 30-day action plan.

A learning simulation using fictional or client-approved, de-identified information.

Delivery, assessment and booking

A training plan shaped around the team and the work they need to perform.

Experienced facilitators

Courses are delivered by consultants with over 50 years' combined GMP experience across pharma, biopharma and advanced therapy manufacturing. Facilitator experience is matched to the agreed course scope.

Flexible delivery

Live online, on-site or blended. We recommend 8-16 participants for practical workshops so each team receives feedback. Larger awareness sessions can be arranged. Confirm facilitator availability and dates when booking.

Evidence of learning

Knowledge checks, practical exercises and facilitator feedback. Longer programmes can include an agreed assessment and workplace follow-up. Attendance certificates or completion certificates following the agreed assessment are issued by Optimal Academy. This catalogue carries no NQF credits or CPD points.

What is included in your proposal

Course scope and learning outcomes, duration, facilitator profile, participant numbers, delivery method, materials and assessment. Travel, venue requirements and any additional coaching are specified separately.

Pricing on request

Share your topic, team size, location and preferred dates.

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Reference frameworks include applicable EU GMP guidance and FDA OOS guidance. Course content is tailored to the client's requirements and controlled procedures.